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In re Application of
LEE et al
Serial No. : 10/720,424
Filed : 24 NOVEMBER 2003
Attorney Ref No. : NEIT0018

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.144, filed on 31 July 2006, to review the restriction requirement. The delay in acting on this petition is regretted.

BACKGROUND

A review of the file history shows that the application was filed on 24 November 2003 with 19 claims.

On 12 January 2006, the examiner required restriction between Group I, product claims 1-12 and 19 and Group II, process claims 13-18. Applicants elected Group I directed to products and is not currently traversing the restriction requirement between product and process inventions.

The restriction requirement mailed 12 January 2006 also required that should Group I or Group II be elected, applicants must then elect of a single pair of primers for examination. Applicants elected the primer pair of SEQ ID No 1 and 8 with traverse. It is this requirement to elect a single primer pair that is now being petitioned.

On 23 March 2006, the examiner mailed an Office action on the merits to applicants in which the traversal was considered but deemed not persuasive. The restriction requirement was made final. Claims 13-18 were withdrawn from examination as being directed to non-elected inventions. Claims 5-12 of Group I were withdrawn as being directed to non-elected primer pairs. Claims 1-4 and 19 were examined with regard to primer pair SEQ ID No 1 and 8.

Claims 1-3 were rejected under 35 USC 102(b) as being anticipated by Brennen.

Claims 1, 2, 3, 4 and 19 were rejected as being unpatentable under 35 USC 103(a) over Gravitt et al, taken in view of Chan et al and Gelfand et al.

DISCUSSION

The application, file history and petition under 37 C.F.R. 1.144, to request review of the restriction requirement has been considered.

The claims are directed to general primers and general primer pairs that amplify and detect Human Papillomavirus (HPV) genotypes which is an oligonucleotide selected from the group consisting of SEQ ID Nos 1-14, or sequences which are fully complementary to SEQ ID Nos 1-14.

Although all the primers amplify a HPV genotype, there are many varying HPV genotypes such that the primers are functionally diverse. Each primers and primer pairs are specific a particular set of genotypes. Thus one primer cannot be substituted for another to get the same effect. For example, the elected primer pair amplifies HPV genotype 1a which is not amplified by primer pairs of SEQ ID No 3 and 10, 4 and 11, 5 and 12, 6 and 13, or 7 and 14. Similarly, the elected primer pair amplifies HPV genotype 2a which is not amplified by primer pairs of SEQ ID Nos 4 and 11.

Moreover, the primers are structurally diverse. A comparison of SEQ ID No 1, 2 and 3, set forth below, shows no significant sequence homology among the primers. A search and examination of each sequence would require a separate query of the appropriate and numerous nucleic acid databases.

<400> 1

gatggtgata tggtagatac aggatttgg 29

<400> 2

ggcgatatgg ttgatacagg ctttg 25

<400> 3

gcacaactat ttaataagcc atattgg 27

A review of the sequence listing shows that some of the sequences are not fully defined in the sequence listing. For example, in SEQ ID No 7, the "n" at position 15 and 21 may be a, c, g or t. The "y" at position 22 may be cytosine or thymine. A search query directed to a partially defined sequence often results in a larger volume of pertinent prior art that requires additional time and effort to review and analyze, this adding to the search and examination burden.

<400> 7

gaggtgggcc ggggncarcc nyt 23

Moreover, all of the sequences are less than 40 nucleotides in length. Such short nucleic acid sequences are often more burdensome to search and examine than longer, more fully defined sequences, because a query directed to a shorter sequence often results in a larger volume of pertinent art which needs to be reviewed and analyzed. Sequences claimed in open terms or functional language, such as "complementary to" also present additional search and examination burden as these phrases read upon fragments and sequences which show only partial alignments.

Applicants argue that the examination of more than one sequence would not be an undue burden on the examiner on the basis that "...to aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et. seq* and permit a reasonable number of sequences to be claimed in a single application...normally ten sequences..." See MPEP 803.04.

Applicants reference to the U.S. Patent and Trademark Office policy regarding the examination of patent applications that claim large numbers of nucleotide sequences in the Official Gazette, 1192 O.G. 68 (November 19, 1996) is acknowledged, however, not found persuasive on the basis that this policy regarding the partial waiving of the requirements of 37 CFR 1.141 is such that it will permit a reasonable number of nucleotide sequences to be claimed in a single application. Under the policy, up to 10 independent and distinct nucleotide sequences will be examined in a single application without restriction. The waiver is permissive and not a requirement. The waiver went into effect in 1996, well before the exponential growth of the nucleic acid databases. The present restriction requirement conforms with this policy as it has required that the application be restricted to a pair of sequences. One primer pair, comprising two sequences, is within the range of up to ten.

DECISION

For these reasons, the petition under 37 C.F.R. 1.144 to request rejoinder of ten primers having SEQ ID Nos 1, 2, 3, 4, 6, 8, 9, 10, 11 and 12 is **DENIED**.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

The application will be forwarded to the examiner to consider the response filed on 23 August 2006.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 571-273-8300.

George Elliott
Director, Technology Center 1600